

## REMARKS

In response to the above-identified Office Action (“Action”), Applicants traverse the Patent Office’s rejection of the claims and seek reconsideration thereof. Claims 1-28, 115-122, 127-128, 132 and 133 are pending in the present application. Claims 29-114, 123-126, 129-131 and 134-137 are cancelled. Claims 1-28, 115-122, 127-128, 132 and 133 are rejected. In this response, claims 1, 4, 10, 13, 22-24, 26-28, 115 and 132 are amended, claims 2, 3, 11 and 133 are cancelled and no claims are added.

### **I. Claim Rejections – 35 U.S.C. §102**

In the Action, claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,456,667 issued to Ham et al. (“Ham”). Applicants respectfully traverse the rejection.

It is axiomatic to a finding of anticipation that each and every element of the rejected claim be found within a single prior art reference.

Independent claim 1 provides the following:

1. A deflectable catheter assembly comprising:
  - a catheter shaft having a catheter proximal section and a catheter distal section, said catheter distal section being more flexible than said catheter proximal section and said catheter proximal section having a length greater than that of the catheter distal section;
  - a tendon disposed within a first lumen of said catheter shaft, said first lumen being approximately centrally located within said catheter shaft along an entire length of said catheter proximal section and said first lumen located off-center of said catheter shaft at said catheter distal section, said tendon being able to deflect said catheter distal section when being pulled on without modifying a length of the catheter shaft;
  - a needle disposed within a second lumen of said catheter shaft, said second lumen being located off-center within said catheter shaft at said catheter proximal section and said second lumen approximately centrally located within said catheter shaft at said catheter distal section;*** and
  - a catheter handle coupled to said catheter shaft, said catheter handle including a first control mechanism to control said tendon. (emphasis added)

Applicants respectfully submit that Ham fails to teach “a needle disposed within a second lumen of said catheter shaft, said second lumen being located off-center within said catheter shaft

at said catheter proximal section and said second lumen approximately centrally located within said catheter shaft at said catheter distal section” as recited in amended claim 1.

Ham describes a catheter with a shaft 11 having an expandable region 12 formed of a tubular material that continues to the distal end of the catheter. See Ham, Abstract. Specifically, Ham discloses a catheter having “an expandable region 12 beginning at the distal end of the catheter body and continuing the catheter body in a one-piece configuration.” See Ham, col. 5, lines 12-15. The distal portion is defined by Ham as extending from side port 21 in sidewall 22 of tubular catheter body 11 to port 23. See Ham, col. 5, lines 23-25. Ham further discloses that expansion of expandable region 12 is controlled by tendon 13.

The Patent Office alleges that “Ham discloses...a catheter shaft (internal compartment 26 or 11) with a proximal section (bottom) and distal (top), a tendon (13) disposed within a first lumen (internal area of 17) which is approximately centrally located at the proximal section (note lumen position is central as it approaches near 44) and at the distal end the lumen is off center (note lumen position is off center as it approaches near top area and numeral 17)...” and “...deflection of the distal end by the tendon (compare figure 1 to 1a).” See Action, page 3.

The Patent Office, however, has not pointed to and Applicants are unable to discern a portion of Ham disclosing a needle, much less a needle disposed within a second lumen located off-center within the catheter shaft proximal section and centrally located within the catheter shaft distal section as required by amended claim 1. Thus, Ham fails to disclose each and every element of claim 1. Since Ham fails to teach each and every element of claim 1, claim 1 is not anticipated by the cited prior art reference. Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §102 over Ham.

## **II. Claim Rejections – 35 U.S.C. §103**

**A.** In the outstanding Action, claims 2-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,123,699 issued to Webster, Jr. (“Webster”) in view of Ham. Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, the Examiner must set forth “some articulated reasoning with some rational underpinning to support the conclusion of obviousness.” See KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007). In combining prior art elements to render the claimed combination of elements obvious, the Examiner must show that the results would have been predictable to one of ordinary skill in the art. See Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103, Section III(D), issued by the U.S. Patent and Trademark Office on October 10, 2007.

Claims 2, 3 and 11 are cancelled therefore the rejection of claims 2, 3 and 11 on this basis is moot.

Claims 4-10 and 12-21 depend from claim 1 and incorporate the limitations thereof. Thus, for at least the reasons previously discussed, Ham fails to disclose at least the elements of “a needle disposed within a second lumen of said catheter shaft, said second lumen being located off-center within said catheter shaft at said catheter proximal section and said second lumen approximately centrally located within said catheter shaft at said catheter distal section” as incorporated into claims 4-10 and 12-21 from claim 1. The Patent Office has further not pointed to, and Applicants are unable to discern, a portion of Webster curing the deficiencies of Ham with respect to each of these elements. Accordingly, the combination of Webster and Ham does not teach or suggest all of the elements of claims 4-10 and 12-21. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4-10 and 12-21 under 35 U.S.C. §103 in view of Webster and Ham.

**B.** In the outstanding Action, claims 22-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Webster in view of Ham in further view of U.S. Patent No. 6,254,598 issued to Edwards et al. (“Edwards”). Applicants respectfully traverse the rejection.

Claims 22-28 depend from claim 1 and incorporate the limitations thereof. Applicants respectfully submit that for at least the reasons previously discussed, the combination of Webster, Ham and Edwards does not disclose or render predictable each of the elements of claims 22-28. In particular, Edwards does not cure the deficiencies of Webster and Ham with respect to the elements of a “a needle disposed within a second lumen of said catheter shaft, said second lumen

being located off-center within said catheter shaft at said catheter proximal section and said second lumen approximately centrally located within said catheter shaft at said catheter distal section” as incorporated into claims 22-28 from claim 1. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 22-28 under 35 U.S.C. §103 in view of Webster, Ham and Edwards.

C. In the outstanding Action, claims 115-122, 127-128, 132 and 133 are rejected under 35 U.S.C. §103(a) as being unpatentable over Webster in view of Ham in further view of Edwards and in further view of U.S. Patent No. 6,770,070 issued to Balbierz (“Balbierz”). Applicants respectfully traverse the rejection.

Claim 133 is cancelled therefore the rejection of claim 133 on this basis is moot.

Claims 115-122, 127-128 and 132 depend from claim 1 and incorporate the limitations thereof. Applicants respectfully submit that for at least the reasons previously discussed, the proposed combination of Webster, Ham, Edwards, and Balbierz does not disclose or render predictable each of the elements of claims 115-122, 127-128, 132 and 133. In particular, Balbierz does not cure the deficiencies of Webster, Ham and Edwards with respect to the elements of “a needle disposed within a second lumen of said catheter shaft, said second lumen being located off-center within said catheter shaft at said catheter proximal section and said second lumen approximately centrally located within said catheter shaft at said catheter distal section” as incorporated into claims 115-122, 127-128 and 132 from claim 1. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 115-122, 127-128 and 132 under 35 U.S.C. §103 in view of Webster, Ham, Edwards, and Balbierz.

## CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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### CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Susan M. Manriquez 9/29/10  
Susan M. Manriquez September 29, 2010